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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER

OU, JING RUI

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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07/10/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/829,507	Applicant(s) UDIPI ET AL.	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-31 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) 21-28 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-20, 29-31, and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment filed on 01/10/2008 and election/restriction response filed on 04/07/2008. Claims 1-7 and 9-31, and 33-40 are pending. Claims 1, 21, 29, and 38 are independent. Claims 21-28 and 38-40 are withdrawn from consideration. Claims 8 and 32 are cancelled.

Election/Restrictions

2. Applicant's election without traverse of Group I (Claims 1-7, 9-20, 29-31, and 33-37) in the reply filed on 04/07/2008 is acknowledged.

Terminal Disclaimer

3. The terminal disclaimer filed on 01/10/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. No. 6,918,929 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 6, 12, 14, 15, 29, 31, and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz (US Pub. No.: 2003/0235602).

In regard to Claim 1, Schwartz discloses a system for treating a vascular condition, comprising: a catheter; a stent coupled to the catheter (a stent must be coupled to the catheter), the stent including a stent framework (Para.[0007]); a polymeric coating disposed on the stent framework, wherein the polymeric coating (barrier layer, Paras.[0006], [0024], [0026], and [0027]) comprises a blended matrix of a polysulfone and a styrenic block copolymer (Para.[0005], [0045], and [0052]); wherein the styrenic block copolymer (copolymer of styrene and maleic anhydride) has a molecular weight of approximately 50,000 (Para.[0021]), and a therapeutic agent in contact with the blended matrix (Paras. [0005], [0006], and [0026]).

In regard to Claim 2, the catheter includes a balloon used to expand the stent (Para.[0007]).

In regard to Claim 6, the therapeutic agent is dispersed within the blended matrix of the polysulfone and the styrenic block copolymer (Paras.[0026], [0045], [0052], and [0062]).

In regard to Claim 12, the therapeutic agent is positioned between the polymeric coating and the stent framework (Paras. [0005], [0006], and [0027]).

In regard to Claim 14, the blended matrix of the polysulfone and the styrenic block copolymer provides a controlled elution rate for the therapeutic agent (Para.[0055]).

In regard to Claim 15, the therapeutic agent is selected from the group consisting of an antirestenotic drug, an antisense agent, an antineoplastic agent, an antiproliferative agent, an antithrombogenic agent, an anticoagulant, an antiplatelet

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agent, an antibiotic, an anti-inflammatory agent, a steroid, a gene therapy agent, a therapeutic substance, an organic drug, a pharmaceutical compound, a recombinant DNA product, a recombinant RNA product, a collagen, a collagenic derivative, a protein, a protein analog, a saccharide, a saccharide derivative, a bioactive agent, a pharmaceutical drug, and a combination thereof (Para.[0033]-[0037]).

In regard to Claim 16, the polymeric coating comprises a plurality of therapeutic agents (Para.[0001]), each therapeutic agent having a predetermined elution rate (Paras.[0012] and [0016])

In regard to Claim 16, the recitation, “the blended matrix of the polysulfone and the styrenic block copolymer eluting the therapeutic agents at the predetermined elution rates” is an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In regard to Claim 29, a drug-polymer coated stent, comprising: a stent framework (Para.[0007]); and a polymeric coating (barrier layer, Paras.[0006], [0024], [0026], and [0027]) disposed on the stent framework, wherein the polymeric coating comprises a blended matrix of a polysulfone and a styrenic block copolymer (Para.[0005], [0045], and [0052]); and a therapeutic agent contacting the polymeric coating (Paras. [0005], [0006], and [0026]), wherein the blended matrix comprises a first fraction of the polysulfone and a second fraction of the styrenic block copolymer based on a predetermined elution rate of the therapeutic agent (Para.[0012], [0024], [0045]).

In regard to Claim 31, it is inherent that the blended matrix comprises a chain length of polysulfone and chain length of styrenic block copolymer since polysulfone and styrenic block copolymer are polymer and copolymer, respectively.

In regard to Claim 33, the therapeutic agent is selected from the group consisting of an antirestenotic agent, an antisense agent, an antineoplastic agent, an antiproliferative agent, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, an antibiotic, an anti-inflammatory agent, a steroid, a gene therapy agent, a therapeutic substance, an organic drug, a pharmaceutical compound, a recombinant DNA product, a recombinant RNA product, a collagen, a collagenic derivative, a protein, a protein analog, a saccharide, and a saccharide derivative (Para. [0034]).

In regard to Claim 34, the therapeutic agent is dispersed within the blended matrix of the polysulfone and the styrenic block copolymer (Para.[0033]-[0037]).

In regard to Claim 35, the therapeutic agent is positioned between the polymeric coating and the stent framework (Paras. [0005], [0006], and [0026]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 3-5 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602).

In regard to Claim 3, Schwartz discloses all the limitations of the claim as taught above but fails to disclose that the catheter includes a sheath.

However, catheter comprising a sheath is old and well known in that art. The suggestion/motivation for including a sheath is to prevent the stent from premature deployment.

In regard to Claims 4, 5, and 30, Schwartz discloses all the limitations of the claims as taught above but fails to disclose that the stent framework comprises one of a metallic base or a polymeric base. Furthermore, Schwartz does not appear to disclose that the metallic base is selected from nitinol.

However, it is old and well known in the art that stent framework comprises one of nitinol or polymeric base. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a stent framework comprising of one of nitinol base or polymeric base, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability from the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Therefore, at the time of the invention, it would have been obvious one of ordinary skill in the art to include a catheter having a sheath and a stent framework comprising of one of nitinol base or a polymeric base to obtain the invention as specified in the instant claims.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) as applied to claim 1 above, and further in view of Chang et al (US Pat. No.: 4,157,960).

Schwartz discloses all the limitations of the claim but fails to disclose that the polysulfone has a molecular weight between 10,000 Daltons and 100,000 Daltons.

However, Chang et al explicitly discloses that the molecular weight of the polysulfone is generally at least about 10,000 and less than about 500,000, and is frequently less than about 100,000 (Col. 8, lines 4-7).

Schwartz and Chang et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Schwartz and Chang et al before him or her, to modify

the system of Schwartz to include polysulfone which has a molecular weight between 10,000 Daltons and 100,000 Daltons.

The suggestion/motivation for doing so would have been that a molecular weight less than 500,000 Daltons is suitable for film or fiber formation (Col. 8, lines 1-7).

Applicant should note that the range of molecular weight for polysulfone applied to stent is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Chang et al with Schwartz to obtain the invention as specified in the instant claim.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) as applied to claim 1 above, and further in view of Pacetti (WO 03/022323).

Schwartz discloses all the limitations of the claim but fails to disclose that the polymeric coating comprises between 0.0 percent and 50 percent of the therapeutic agent by weight.

However, Pacetti explicitly teaches that a polymeric coating comprises between about 0.1% to about 40% of the therapeutical agent by weight (Para.[0026]).

Schwartz and Pacetti are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a polymeric coating comprising between about 0.1 % to about 40% of the therapeutic agent by weight as taught by Pacetti.

Applicant should note the range of percentage of the therapeutical agent by weight in polymeric coating is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Pacetti with Schwartz to obtain the invention as specified in the claim.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) as applied to claim 1 above, and further in view of Cafferata (US Pub. No.: 2003/0083739).

Schwartz discloses all the limitations of the claim but fails to disclose that the polymeric coating has a thickness between 0.5 microns and 20 microns.

However, Cafferata specifically teaches a polymeric coating that has a thickness between approximately 1 micron and about 20 microns (Para.[0035]).

Schwartz and Cafferata are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a polymeric coating that has a thickness between approximately 1 micron and about 20 microns as taught by Cafferata.

Applicant should note the range of thickness of the polymeric coating is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Cafferata with Schwartz to obtain the invention as specified in the claim.

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13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) as applied to claim 1 above, and further in view of Hossainy et al (US Pat. No.: 6,153,252).

Schwartz discloses all the limitations of the claim but fails to disclose that the polymeric coating has a weight between 50 micrograms and 1500 micrograms.

However, Hossainy et al discloses a stent comprising a polymeric coating which has a weight between about 100-150 micrograms (Col. 11, lines 2-8).

Schwartz and Hossainy et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a polymeric coating that has a weight between approximately 100-150 micrograms as taught by Hossainy et al.

Applicant should note the range of weight of the polymeric coating is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Hossainy et al with Schwartz to obtain the invention as specified in the claim.

14. Claims 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602) as applied to claim 1 above, and further in view of Sirhan et al (US Pub. No.: 2003/0083646).

In regard to Claim 13, Schwartz discloses all the limitations of the claim but fails to disclose that the therapeutic agent has a thickness between 0.1 microns and 20 microns.

However, Sirhan et al discloses a stent (expandable structure, 16, Fig. 2A) comprising a therapeutic agent that has a thickness between 0.1 microns and 5 microns (Para.[0025]).

Schwartz and Sirhan et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a therapeutic agent that has a thickness between 0.1 microns and 5 microns as taught by Sirhan et al.

Applicant should note the range of thickness of the therapeutic agent is only a design choice and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Sirhan et al with Schwartz to obtain the invention as specified in the claim.

In regard to Claims 16-18, Schwartz discloses all the limitations of the claims but fails to explicitly disclose that the polymeric coating comprises a plurality of therapeutic agents, each therapeutic agent having a predetermined elution rate. Schwartz does not appear to disclose that the first therapeutic agent is concentrated adjacent to the stent framework, and a second therapeutic agent is concentrated adjacent to the outer surface of the polymeric coating. Furthermore, Schwartz does not appear to disclose that the first therapeutic agent comprises an antirestenotic drug and the second therapeutic agent comprises an anti-inflammatory drug.

However, Sirhan et al explicitly teaches a stent (16, Fig. 2K) comprising a polymeric coating which comprises a plurality of therapeutic agents (50 and 28, Fig.

2K), each therapeutic agent having a predetermined elution rate (the rates are controlled by the rate controlling element 43 and 55, Para.[0106]). Sirhan et al also explicitly teaches that the first therapeutic agent (28, Fig. 2K) is concentrated adjacent to the stent framework, and a second therapeutic agent (50, Fig. 2K) is concentrated adjacent to the outer surface of the polymeric coating. Furthermore, Sirhan et al explicitly teaches that the first therapeutic agent comprises an antirestenotic drug (rapamycin, Paras.[0087]) and the second therapeutic agent comprises an anti-inflammatory drug (Para.[0107]).

Schwartz and Sirhan et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a plurality of therapeutic agents, a predetermined elution rate for each therapeutic agent, the first therapeutic agent is concentrated adjacent to the stent framework, and a second therapeutic agent is concentrated adjacent to the outer surface of the polymeric coating, and the first therapeutic agent comprises rapamycin and the second therapeutic agent comprises an anti-inflammatory drug as taught by Sirhan et al.

It is old and well known in the art that a stent comprises a polymeric coating which comprises a plurality of therapeutic agent and each therapeutic agent having a predetermined elution rate. The suggestion/motivation for doing so would have been to deliver more than one therapeutic agent to the body at different rate to maximum the therapeutic effect in the body and therapeutic need by the body.

Applicant should note the first therapeutic agent is concentrated adjacent to the stent framework, and a second therapeutic agent is concentrated adjacent to the outer surface of the polymeric coating, and the first therapeutic agent comprises rapamycin and the second therapeutic agent comprises an anti-inflammatory drug are only design choices and within the level of one of ordinary skill in the art.

Therefore, it would have been obvious to combine Sirhan et al with Schwartz to obtain the invention as specified in the claims.

15. Claims 19, 20, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable Schwartz (US Pub No.: 2003/0235602) as applied to claims 1 and 29 above, and further in view of Hossainy et al (US Pub. No.: 2001/0014717).

In regard to Claims 19, 20, 36, and 37, Schwartz discloses all the limitations of the claim but fails to disclose a primer coating.

However, Hossainy et al explicitly teaches a primer coating disposed on the surface of an implantable device between the implantable device and a reservoir region (Para.[0015]). Hossainy et al further discloses that the primer coating is formed by polyurethane (Para.[0041]).

Schwartz and Hossainy et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include a primer coating formed by polyurethane as taught by Hossainy et al.

Applicant should note that it is old and well known in the art that a primer coating is formed between a stent framework and a polymeric coating. The motivation/suggestion for doing so would have been to provide an adhesive tie layer for the stent framework and the drug reservoir layer or the polymeric coating (Hossainy et al, Para.[0015]).

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to form a primer coating with polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Therefore, it would have been obvious to combine Hossainy et al with Schwartz to obtain the invention as specified in the claims.

16. Claims 28 is rejected under 35 U.S.C. 103(a) as being unpatentable Schwartz (US Pub No.: 2003/0235602) as applied to claim 21 above, and further in view of Hossainy et al (US Pub. No.: 2001/0014717).

In regard to Claim 28, Schwartz discloses all the limitations of the claim but fails to disclose applying a primer coating onto the stent framework prior to applying the polymeric solution on the stent.

However, Hossainy et al explicitly teaches applying a primer coating onto the stent framework prior to applying the polymeric solution on the stent (Para.[0083]-[0089]).

Schwartz and Hossainy et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Schwartz to include applying a primer coating onto the stent framework prior to applying the polymeric solution on the stent as taught by Hossainy et al.

Applicant should note that it is old and well known in the art that a primer coating is formed between a stent framework and a polymeric coating. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to apply a primer coating onto the stent framework prior to applying the polymeric solution on the stent. The motivation/suggestion for doing so would have been to provide an adhesive tie layer for the stent framework and the drug reservoir layer or the polymeric coating (Hossainy et al, Para.[0015]).

Therefore, it would have been obvious to combine Hossainy et al with Schwartz to obtain the invention as specified in the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING RUI OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

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